

**MEDICAL LABORATORY BOARD
MINUTES**

Date: October 14, 2004

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, MT Chairman
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Martha Duncan, Medical Technologist
Charles R. Handorf, MD
Sharon Hargrove, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald, Cytotechnologist
Debbie Stinnett, Medical Technologist

Members Absent: Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Delores Voigt, MT Hospital Administrator
Monya Faye Pryor, Citizen Representative

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent: Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office

Quorum:

A sufficient number of board members were present to constitute a quorum.

Presiding Officer:

The meeting was called to order by Chairmen, Kelly S. Terry at 9:05 a.m. Board Members introduced themselves to the audience.

Board Minutes:

A motion to approve the July 15, 2004 Full Board minutes was made by Dr. Handorf with a second to the motion by Dr. McDonald. The minutes were approved.

A motion to approve the Personnel & Education Committee minutes from the July 14, 2004 meeting was made by Dr. Handorf. A second to the motion was made by Dr. McDonald. The Committee minutes were approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of actions from the Personnel & Education Committee meeting held on October 13, 2004. A motion to accept this report was made by Ms. Duncan. A second to the motion was made by Ms. Hargrove. The motion carried and the actions of the Committee were approved.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN
TNPAP State Director

Mr. Harkreader was introduced as the new director for this professional advocacy program. The contract for the 2004-2005 calendar years was approved by the Department. A copy of Mr. Harkreader's report is on file in the Board's administrative office.

A motion to approve this report was made by Ms. Lahr with a second to the motion by Ms. Stinnett. The motion carried.

Board Report-Rules:

Jerry Kosten-Rules Manager
A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held September 23, 2004 concerning the following amendments to:

- 1- . Rules 1200-6-3-.05 concerning Licensure Discipline, Civil Penalties, Assessment of Costs and Subpoenas for medical laboratory facilities and
- 2- Rule 1200-6-3-.15 concerning Special Regulations for ambulatory surgical Treatment centers (ASTC's), blood donor centers and plasmapheresis centers.

There were no comments presented to Mr. Kosten during the rulemaking hearing.

A motion to adopt these amendments was made by Dr. Handorf with a second to the motion by Ms Lahr.

A roll call vote was taken with all members present voting aye.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing to be held on December 12, 2004 for:

- 1- Rules 1200-6-1 concerning continuing education requirements (CEU's) for Medical Laboratory Personnel renewal, retirement and reactivation of licenses.
- 2- Rules 1200-6-1 regarding the issuance of temporary licenses.
- 3- Rules 1200-6-3 regarding medical laboratory facilities ordering of outpatient laboratory tests.

A motion to authorize this rulemaking hearing was made by Dr. Handorf with Dr. McDonald providing a second to the motion. The motion carried.

Contested Case:

There was no contested case during this board meeting.

Ratification of Formal Reprimand:

Earl B. Farabee, MT
Memphis, TN
License #2652
Supervisor-Clinical Chemistry

The board was presented with documentation of a Letter of Reprimand resulting from an investigation revealing that Mr. Farabee performed supervisory duties from November 1997 until December 2003. Mr. Farabee did not possess a Medical Laboratory Professional-Supervisor General license. This is a violation of Tennessee Code Annotated Section 68-29-101 et seq. A motion to ratify this formal reprimand was made by Dr. Handorf with a second to the motion by Ms. Lahr. The motion carried.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, contact with TNPAP for peer assistance services, upcoming rulemaking hearings, legislative actions, website updates, and facility closures. The complete report is on file in the administrative office.

A motion to accept Ms. England's report was made by Dr. Handorf. A second to the motion was made by Ms. Duncan. The motion carried.

Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab Facilities:

There were no requests presented to the board for review during the October meeting.

Reinstatement of License:

There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

1-Regional Consultant/Surveyor – Proficiency Testing (PT)
Complaints on Licensed Laboratory Facilities

A. East Tennessee Regional Office-Onezean Otey, Consultant I/Surveyor

Unsatisfactory or Unsuccessful Proficiency Testing:

The East Tennessee Regional office has no unsuccessful proficiency testing to report to the Medical Laboratory Board for the third quarter of 2004.

Complaints:

There was one (1) complaint to report concerning a phlebotomy incident. The complaint was confirmed and the laboratory supervisor counseled the laboratory staff and re-trained the phlebotomist on proper PKU collection.

B. Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor
Irmgard A. Brown, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is three (3):

Analytes: 1st Laboratory-CKMB
2nd Laboratory-HB's Ag, Anti-HBc, Triglyceride

3rd Laboratory-HBs Ag

The number of state licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events (three out of four/three in a row): none (0).

Complaints:

The Middle Tennessee Regional Office has conducted one (1) complaint investigation during this quarter. The complaint was unsubstantiated.

C. West Tennessee Regional Office-Karen Daniels, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): none (0).

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

A motion to approve all three (3) of these reports was made by Dr. Handorf with a second to the motion by Ms. Duncan. The motion carried.

2-Amy Webster MT (ASCP)

Memphis Pathology Laboratory (MPL) Compliance & Privacy Officer

Ms. Webster made an appearance before the board concerning these two (2) issues:

a- The results of “within normal limits” Pap smear (Cytology-Gyn) being mailed by the contracting laboratory to the ordering physician and also a letter with the results directly to the patient. This situation is commonplace by some independent laboratories and perhaps some hospital based laboratories in this state. She asked the board to evaluate this practice with current medical laboratory regulations.

The board noted this practice is a direct violation of the state statute, Tennessee Code Annotated §68-29-121(b) in that the “results of a laboratory test shall be reported to the physician, optometrist, dentist, chiropractic physician or other health care professional who requested it.”

The suggestion was made that the laboratory contract with the authorizing physician to allow the laboratory to send the results **for the physician** (the laboratory acts as an agent of the physician).

Another board suggestion was to have the laboratory send the test results to the physician and the physician mail the results to the patient. There will be a note put with the 2005 laboratory facility renewals regarding this discussion.

If further clarification is necessary a declaratory order for rule interpretation could be presented for board review.

b-A second question concerned the licensing of collection stations:

Service Centers of MPL:

There are six (6) service centers in the Memphis area that are collection stations owned and operated by MPL. Blood and urine specimens are collected from these sites but are not sent to laboratories outside Tennessee. All samples are sent via courier to MPL core laboratory. The board determined these sites are not subject to licensure because specimens are sent to licensed in-state laboratory. However these patient service centers (PSC's) are subject to On-site inspections at the time as a part of the regular laboratory compliance survey.

MPL Phlebotomists in Physician Offices:

This licensed laboratory also provides phlebotomists on a contractual basis to physician office locations in and around the Memphis/Shelby county area. The phlebotomists are MPL employees who provide services to the patients of that physician's practice only with no outside referrals. These services may be for the collection and processing of MPL specimens, however insurance providers may request laboratory specimens be forwarded to labs other than MPL. A courier from that other laboratory may pick up the specimen and take the specimen to a collection station where it may be packaged and mailed outside the state of Tennessee.

After discussion, the board decided not to license these MPL-contracted physician draw centers at this time.

3. Further clarification of FISH Testing Procedures:

During the July 2004 meeting, the board was asked to clarify the qualifications for personnel performing the FISH (Fluorescence In-Situ Hybridization) test. After discussion the board declared:

"The Committee found it appropriate to allow molecular pathology techniques (ex. FISH) which are applied to tissue or cells to be viewed as a histologic test as long as each and every test is reviewed, interpreted and reported by a pathologist."

During this October meeting it was determined, the pathologist must pick all cells to be reviewed during this test procedure. Any FISH test performed on a urine sample becomes cytological in nature and the pathologist must look at all cells and choose those appropriate for the diagnosis. Individuals not licensed as a physician performing cell interpretation in this manner is guilty of practicing medicine without a license.

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell provided the board with a 2004 OGC Monthly Report Board Summary of new, closed and open cases for each professional licensing board.

A motion to accept this report was made by Dr. Handorf with a second to the motion provided by Ms. Stinnett. The report was approved.

Office of General Counsel Report:

Robert J. Kraemer, Jr.

Advisory Attorney

Mr. Kraemer led the discussion of the following items:

1. **Dental Lab Director (03-1111)** The rulemaking hearing was held on December 23, 2003; this amendment was adopted by the Board on January 15, 2004 and was sent to the Attorney General on January 27, 2004. The amendment was signed by the Attorney General and filed with the Secretary of State on July 8, 2004 and became effective September 21, 2004.
2. **Temporary Permits & Cleanup (04-1037)** The rulemaking hearing was held on March 19, 2004 and this amendment was adopted by the Board on April 15, 2004 and was sent to the Attorney General on April 22, 2004. It is still there.
3. **Hematology Controls (04-1192)** The rulemaking hearing was held on July 8, 2004 and the Board adopted the amendment on July 15, 2004. It went to the Attorney General on July 21, 2004 and is still there.
4. **Screening Tests and Civil Penalties (04-1378)** The rulemaking hearing was held on September 23, 2004 and after response comments, these amendments are ready for adoption at this meeting.

Litigation:

The Office of General Counsel currently has eight (8) open disciplinary cases pertaining to the Medical Laboratory Board.

A motion to accept this report was made by Dr. Handorf with a second by Ms. Duncan. The motion carried.

Bureau of Investigations (BIV) Report:

Lea Phelps
Disciplinary Coordinator

Documentation was presented for board review concerning the number of cases in the Bureau of Investigation.

Ms. Phelps distributed the disciplinary report to the Board members, noting that the list comprised disciplinary actions on licensees beginning in July 1996 through November 2001.

A motion to accept this report was made by Ms. Hargrove with a second to the motion made by Ms. Stinnett. The motion carried.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is on file in the administrative office.

Waived Testing Procedures:

After Board discussion, a motion to add (CLIA waived) Influenza A & B determinations to the point of care state waived test list. This motion made by Dr. Handorf with a second by Ms. Cooper. The motion carried.

Point of Care Task Force:

This task force continues to meet but no inquiries were made to the board during this meeting.

Review Eligibility of Medical Laboratory Director:

1. Lydia E. McMorrow, Ph.D.
Trenton, NJ
Director-Cytogenetics

Ms. Thacker informed the Board Dr. McMorrow's file was complete and she has met the requirements for licensure in the category of Director of Clinical Cytogenetics. The applicant holds a Ph.D. degree in the clinical specialty of Biology and possesses national boarding in Clinical Cytogenetics with the American Board of Medical Genetics. Dr. McDonald made a motion to approve this application. A second to the motion was made by Ms. Hargrove. The motion carried.

2. Richard E. Mullins, Ph.D.
Arlington, TN
Director-Clinical Chemistry

Ms. Thacker informed the Board Dr. Mullins holds a Ph.D. in Chemistry and holds boarding by the American Board of Bioanalysis as a Bioanalyst Clinical Laboratory Director (BCLD). A motion to approve this application for licensure as a Director-Clinical Chemistry was made by Ms. Hargrove with a second to the motion by Ms. Lahr. The motion carried.

Other Business:

The term for Ms. Sharon Hargrove to serve on this board expires on December 31, 2004. Ms. Hargrove served in the representative capacity of independent laboratory management/administration medical laboratory professional. On behalf of the board and administrative staff, Ms. Terry presented Ms. Hargrove with a memento representing her contribution and service in being a member of this Committee.

Statement of Next Meeting:

The next meeting will be held on January 13, 2005 beginning at 9 am, CST in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 1:45 p.m. on a motion properly presented by Dr. Handorf and seconded by Ms. Hargrove. The motion carried.

Kelly S. Terry, MT
Board Chairman

Date

Attachment 1
Medical Lab Board
Point of Care Exemption Requests
October 14, 2004

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. T.C, Thompson Children's Hospital
910 Blackford Street
Chattanooga, TN 37403-1405

Facility Representative: Dianna Geren

Operations Manager

This facility request was for:

1-Licensed Respiratory Therapists to perform and report pH, PO₂, PCO₂, sodium, potassium, chloride, CO₂, ionized calcium, glucose, hematocrit, BUN and creatinine in the Pediatric Intensive Care Unit utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. Handorf with a second to the motion by Dr. McDonald. The motion carried.

2-Licensed Registered Nurses (RN's & LPN's) to perform and report pH, PO₂, PCO₂, sodium, potassium, chloride, CO₂, ionized calcium, glucose, hematocrit, BUN and creatinine in the Children's Hospital Surgical Unit to include the Surgical Suite, Recovery and Pre-Op Units utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The motion carried.

3-Licensed Respiratory Therapists, in response to Pediatric Codes, to perform and report pH, PO₂, PCO₂, sodium, potassium, chloride, CO₂, ionized calcium, glucose, hematocrit, BUN and creatinine utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

2. Methodist University Hospital
1265 Union Avenue
Memphis, TN 38104

Facility Representative: Harriett Bateman

This facility request was for Registered Nurses (RN's) to perform and report activated clotting times, (ACT's) in the Interventional Radiology Unit utilizing the Hemochron instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Stinnett. The motion carried.

Note: Ms. Terry and Dr. Handorf recused themselves from this discussion and vote.

3. Fort Sanders Regional Medical Center
1901 Clinch Avenue
Knoxville, TN 37916

Facility Representative: Debra Ogle, MT
POCT Tech Specialist

This facility made the following exemption requests:

1-Perfusionists to perform and report arterial blood gases (ABG's), sodium, potassium, ionized calcium and hematocrit determinations during cardiac surgery utilizing the i-STAT instrument and methodologies in the Surgical Operating Rooms, Recovery Areas and Holding Areas.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Duncan. The motion carried.

2-Perfusionists and Surgery Nurses (RN's & LPN's) to perform and report activated clotting times (ACT's) in all vascular surgery and cardiac surgery procedures as needed, utilizing the Hemochron instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Stinnett. The motion carried.

4. Dynacare Tennessee
1924 Alcoa Highway
Knoxville, TN 37920

Facility Representative: Jacqueline Christie, MT (ASCP), CLSup
Point of Care Coordinator/QA Analyst

This request was for Respiratory Therapists to perform and report prothrombin times (PT's) utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Cooper. The motion carried.

5. Maury Regional Hospital
1224 Trotwood Avenue
Columbia, TN 38401

Facility Representative: Amy Bridges, MT
Point of Care Coordinator

This exemption request was for Certified Respiratory Therapists to perform blood gases, electrolytes, glucose, BUN, creatinine, hematocrit and ionized calcium throughout this facility. The instrument and methodologies utilized is the i-STAT.

A motion to approve this request was made by Dr. Handorf with a second to the motion by Dr. McDonald. The motion carried.

6. Diagnostic Laboratories-VUMC

22nd & Pierce 4605 TVC
Nashville, TN 37232-5310

Facility Representative: Terry Tubb
Point of Care Coordinator

This facility requested the following exemptions from the board:

1-Laboratory Liaison Technician II to perform and report Rapid Influenza testing procedures in the adult ED of VUMC and also the pediatric ED of VUCH utilizing the Quidel Quick Vue Test Kit.

A motion to approve this request was made by Dr. Handorf with a second to the motion by Ms. Stinnett. The motion carried with the majority of board members voting aye. Ms. Lahr voted nay.

Note: Later in the meeting the Board voted to add this test procedure to the Waived Test List for Point of Care Testing Procedures.

2-Registered Nurses (RN's) and Certified Anesthesiology Technicians to perform and report pH, blood gas, potassium, glucose, ionized calcium and hematocrit in the Operating Suites.

A motion to approve this request was made by Dr. Handorf. A second to the motion was made by Ms. Stinnett. The motion carried.

7. Centennial Medical Center
2300 Patterson Street
Nashville, TN 37203

Facility Representative: Mollie Wynn, MT(AMT)
POC Coordinator
Carolyn Hick

This facility made a request to exempt the following procedures:

1-Registered Nurses (RN's & LPN's) and Perfusionists to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin and hematocrit in the Cardiovascular OR utilizing the Bayer 405 instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Hargrove. The motion carried.

1a-Registered Nurses (RN's & LPN's) and Perfusionists to perform and report activated clotting times (ACT's) in the Cardiovascular OR utilizing the ITC Signature Elite instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to this motion by Ms. Hargrove. The motion carried.

2-Registered Nurses (RN's & LPN's) to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin and hematocrit in the Cardiovascular Intensive Care Unit utilizing the Bayer 405 instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

2a-Registered Nurses (RN's & LPN's) to perform and report activated clotting times (ACT's) in the Cardiovascular Intensive Care Unit utilizing the ITC Signature Elite.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

3-Registered Nurses (RN's & LPN's) to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin and hematocrit in the Cardiac Care Unit utilizing the Bayer 405 instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

3a-Registered Nurses (RN's & LPN's) to perform and report activated clotting times (ACT's) in the Cardiac Care Unit utilizing the ITC Signature Elite instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

4-Registered Nurses (RN's & LPN's) and Perfusionists to perform and report oxygen saturations in the Cardiac Cath Laboratory utilizing the Bayer 405 instrument and methodologies.

A motion to approve this request was made by Dr. Handorf and a second to the motion by was made by Dr. McDonald. The motion carried.

4a-Registered Nurses (RN's & LPN's) and Perfusionists to perform and report activated clotting times (ACT's) in the Cardiac Cath Laboratory utilizing the Hemachron Signature Elite instrument and methodologies.

A motion to approve this request was made by Dr. Handorf with a second to the motion by Dr. McDonald. The motion carried.

Note: Ms. Duncan and Ms. Stinnett recused themselves from this discussion and vote.

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION

1. St. Francis Hospital-Bartlett
2986 Kate Bond Road
Bartlett, TN 38133

Medical Laboratory Director: Justin C. Adler, M.D.
Anatomic/Clinical Pathology

Specialties: Bacteriology, Parasitology, General Immunology, Clinical
Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology,
Immunohematology, Pathology

Surveyor: Mary J. Hamblen, MT Consultant II/Surveyor
West TN Regional Office

A motion to approve this request was made by Dr. Handorf with a second to this motion by Ms. Lahr. The motion carried.

2. Advanced Toxicology Network-Clinical Laboratory
3560 Air Center Cove
Memphis, TN 38118

Medical Laboratory Director: Pamela Osborne, M.D.
Anatomic/Clinical Pathology

Specialties: Diagnostic Immunology, Clinical Chemistry, Urinalysis, Endocrinology,
Hematology

Surveyor: Mary J. Hamblen, Consultant II/Surveyor
West TN Regional Office

A motion to approve this request was made by Ms. Hargrove with a second to the motion by Ms. Duncan. The motion carried.

3. Select Specialty Hospital-University of Tennessee Campus
1924 Alcoa Highway 7th Floor
Knoxville, TN 37920
Medical Laboratory Director: Michael McCormack, M.D.

Pulmonology

Specialties: Arterial Blood Gases & pH

Surveyor: Onezean Otey, Consultant I/Surveyor
East TN Regional Office

A motion to approve this facility for licensure was made by Dr. McDonald. A second to the motion was made Ms. Allison McDonald. The motion carried.

4. Ameritox Patient Service Center
501 Metroplex Drive Suite 106
Nashville, TN 37211

Medical Laboratory Director: Rose A. Payne, M.D.

Specialties: Collection Station

Surveyor: Sandra S. Bogard, MT Consultant II/Surveyor
Middle TN Regional Office

A motion to approve this facility for licensure was made by Dr. Handorf. A second to the motion was made by Ms. Stinnett. The motion carried.

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